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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1610.1US01	6766

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ALTERA LAW GROUP, LLC
6500 CITY WEST PARKWAY
SUITE 100
MINNEAPOLIS, MN 55344-7704

EXAMINER	
HON, SOW FUN	

ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/475,721	REIMINK ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-20,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-20,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 23, 2004 has been entered. Applicant's new representative is noted.

Rejections Repeated

2. The 35 U.S.C. 102(b) rejection of claims 1-8, 10-19, 31 as being anticipated by Pietsch et al. is repeated for the same reasons previously of record in the action dated 07/28/03.

3. The 35 U.S.C. 103(a) rejection of claim 20 over Pietsch et al. in view of Sumimoto Electric Co. is repeated for the same reasons previously of record in the action dated 07/28/03.

4. The 35 U.S.C. 103(a) rejection of claims 9, 32 over Pietsch et al. in view of MacGregor is repeated for the same reasons previously of record in the action dated 07/28/03.

Response to Arguments

5. Applicant's arguments filed January 23, 2004 have been fully considered but they are not persuasive.

6. Applicant argues that the support ring of Pietsch et al. is part of the structure that provides the form of the device because the support ring and the cusps are formed integrally as a

result of the plastic skin, from which the cusps are formed, which also enclose the support ring, the support ring being composed of only polymer, no organic substrate being present.

Applicant is respectfully informed that Peitsch et al. teaches that the support ring can be made out of inorganic material (stainless steel, ceramics) (column 10, lines 10-15). Applicant is respectfully directed to the embodiment below.

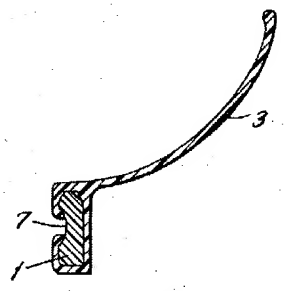

FIG.3

In Fig. 3, Pietsch et al. shows a cross-sectional view of the heart valve whereby the cusp material 3 encloses the support ring 1, and that the boundary edge of the cusp has a rounded lobar thickened outline (column 8, lines 20-30). It can be seen that the cusp 3 provides the form of the device. The cusp is made of flexible three-dimensionally crosslinked polymer (column 4, lines 20-30). The support ring is made out of inorganic material (stainless steel, ceramics) (column 10, lines 10-15). Thus it can be seen that the polymer (cusp material) itself, and not the inorganic substrate, provides the form of the device.

7. Applicant argues that the cusps of Pietsch et al. are flexible, but are not made of a substrate and polymer composite. Applicant is directed to Fig.3 above which shows that the cusp 2 extends all the way down, around and up over the support ring 1, which is a substrate and polymer composite. The claim limitation of "a medical device comprising a flexible composite

component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate" is very broadly encompassing.

8. Applicant argues that "deformable elastic" is not the same as flexible which is made clear by Pietsch et al. in that the support ring only supports the lower part of the valve while the upper part of the cusps and their joining zones remain free and flexible.

Applicant is respectfully reminded that the claim limitation of "a medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate" is very broadly encompassing in terms of structure. It is suggested that Applicant amend the claims to reflect the structures in the original drawings which are part of the specification.

9. Applicant argues that Pietsch et al. does not disclose a composite that can be bent at least about 100 degrees without extending the material beyond its elastic limit.

Applicant is respectfully reminded that the evidence is present to indicate that the three-dimensionally crosslinked polydimethylsiloxane can be bent by at least 100 degrees while remaining elastic, and by about 180 degrees without extending beyond its elastic limit. The evidence is the teaching by Pietsch et al. that the three-dimensionally crosslinked polydimethylsiloxane has high fatigue strength in alternate bending, high breaking strength of at least 8 N/mm^2 at a low Shore A hardness of 25-35, and an elongation at break of more than 400 % (column 4, lines 60-65). The elastic limit of a material is defined below, wherein the deformation of the material is recoverable within the limit of the strain at the elastic limit. Pietsch et al. is stating that when a piece of the silicone rubber (crosslinked

polydimethylsiloxane) is bent, or strained, it goes back to its original shape upon release of the bending force (strain) unless the force (or strain), is at least 8 N/mm^2.

10. Applicant argues that no inorganic substrate is disclosed or taught that, together with a polymer, forms a flexible composite that can be bent at least about 100 degrees without extending the composite beyond its elastic limit.

Applicant is again respectfully reminded that the claim limitation of "a medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate" is very broadly encompassing in terms of structure. It is suggested that Applicant amend the claims to reflect the structures in the original drawings which are part of the specification.

11. Applicant argues that instead of Pietsch et al, MacGregor is the reference which teaches the structure in the claim limitation of "a medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate". Applicant is respectfully apprised that both references teach the same limitation which is broadly encompassing.

12. Applicant argues that while it is true that the cusp material encloses the support ring of Pietsch et al., the skin that also forms the cusps follows the contour of the support ring, including the groove, and thus the support ring also provides the shape or form of the heart valve.

Applicant is respectfully apprised that it would be extremely difficult to envision the support ring as providing the shape or form of the heart valve without the cusps.

13. Applicant argues that while it is true that the cusp in Pietsch et al. is made up of a polymeric material which extends all the way down, around and up over the support ring, which

is made of a substrate material, Pietsch et al. does not teach or disclose that the support ring covered with the polymeric skin is flexible.

Applicant is again respectfully reminded that the claim limitation of "a medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate" is very broadly encompassing in terms of structure. It is suggested that Applicant amend the claims to reflect the structures in the original drawings which are part of the specification.

14. Applicant argues that Pietsch et al. actually teaches away from a flexible composite when they teach that the function of the support ring is to provide support to the flexible cusps to prevent the flapping over of the valve and to anchor the suture ring.

Applicant is again respectfully reminded that the claim limitation of "a medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate" is very broadly encompassing in terms of structure. It is suggested that Applicant amend the claims to reflect the structures in the original drawings which are part of the specification.

15. Applicant argues that the composite of MacGregor is formed into the shape of the device, suggesting that the medical device of MacGregor actually meets the claim limitation of "a medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate".

Applicant is respectfully requested to confirm by specifically referencing each component to the specification of the present application. The specification includes the original drawings.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sow-Fun Hon
03/25/04

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

3/29/04